

### **REMARKS**

#### **Status of the Claims:**

Claims 1-24 were submitted with the originally filed specification. A restriction requirement was made by the Examiner and Claims 1-21 have been elected, with traverse, by the Applicant. Thus, originally submitted claims 1-21 are pending in this application. The Applicant reserves the right to submit non-pending claims 22, 23 and 24 in divisional applications.

Claims 1-21 have been rejected in the Office Action. Reconsideration of the Examiners' rejection is hereby respectfully requested in light of the following remarks.

#### **Rejection Under 35U.S.C. §103**

Claims 1-6 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 5,976,555. The Examiner states that the components of the skin care composition and the general processes of heating, mixing, vacuum and cooling are described in the '555 patent. It is the Examiners' contention that one skilled in the art could modify the process and formulation disclosed in the '555 patent to achieve the presently described invention.

The pending claims describe a superior process to prepare a skin softening topical composition. The process is an anhydrous method, and because of the nature of the components of the composition, no water can be present in the process. If water is present, the active ingredients of the resultant anhydrous skin softening composition degrade. Specifically, as described in the pending applications' specification, water provides for the degradation of urea into ammonia and carbon dioxide and enables the migration of salicylic acid out of the emulsion, thereby decreasing the shelf life of the composition. The inventive process, as described and claimed, results in a storage stable, anhydrous emulsion containing therapeutic amounts of urea and salicylic acid.

In contrast, the '555 patent describes an oil-in-water emulsion containing retinoids. The patent also discloses the use of a myriad of other excipients, including small amounts of antioxidants and preservatives. The list of antioxidants and preservatives include thiourea, diazolidinyl urea and salicylic acid. The examiner

specifically points to example 7, which describes the use of diazolidinyl urea in an emulsion. Diazolidinyl urea breaks down in aqueous, topical formulations and releases formaldehyde to act as an antibacterial/antimicrobial. In contrast, the claimed process is designed to prevent the chemical degradation of the active ingredients.

There are many differences between the prior art and the claims at issue. First, the pending claims provide for an anhydrous process to prepare an anhydrous emulsion. The prior art is to a hydrous composition of an oil-in-water emulsion. The pending claims describe a process to prepare a stable composition of urea and salicylic acid. The prior art provides a long list of possible excipients that may include diazolidinyl urea and salicylic acid as antimicrobials. The diazolidinyl urea of the prior art is meant to chemically break down to release formaldehyde. The prior art describes salicylic acid as an excipient, not as a therapeutic agent. The prior art specification does not provide for the active pharmaceutical ingredient, urea, nor for therapeutic amounts of salicylic acid. The importance of the present process is that the urea does not decompose during the process, and the salicylic acid does not crystallize out of the anhydrous emulsion. There is no suggestion or motivation to look to the '555 patent, which teaches an oil-in-water emulsion, to provide an improved anhydrous process to prepare an anhydrous emulsion. Additionally, there is no teaching in the prior art to teach one of ordinary skill an anhydrous process that creates a topical composition containing stable, therapeutic amounts of urea and salicylic acid.

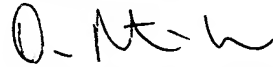
Claims 7-21 have been objected to as being dependent upon a rejected base claim. The Examiner has stated that he would find these claims allowable if rewritten in independent form. The applicant respectfully requests the removal of the rejection in light of the above discussion and allowance of all pending claims.

### **Conclusion**

In view of the foregoing remarks the Applicant respectfully submits that the grounds of rejections stated against the claims under 35 U.S.C. §103 have been overcome and the claims are now in condition for allowance. Favorable action is earnestly solicited.

If the Examiner has any questions concerning the application, he is requested to call the Applicants' agent at 914-345-9001, ext. 6365.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "D. R. Chow".

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Agent for Applicant

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